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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,462	11/13/2003	Jan Otto Solem	51533/MEG/E303	2503
30452 7590 06/15/2007 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 06/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/714,462

Applicant(s)

SOLEM ET AL.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,11,13,14 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 15-25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,8,11,13,14 is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/4/06;8/25/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Response to Restriction

Applicant's election of group 1 in the reply filed on 11/15/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra (USPN 5,170,802, as cited in applicant's IDS) in view of Dahl et al. (USPN 5,531,779).

Mehra discloses an assembly with all the elements of claim 1, but is silent specifically to the device reshaping the mitral valve annulus when in the coronary sinus of the heart. See Figures 1, 5 and 6, column 3, lines 34-36 and column 4, lines 8-40 for an assembly including a guide wire (118) configured to be advanced to the coronary sinus (12) and a device (100) in the form of a self-expanding electrode configured to be received on the guide wire (118) and advanced into the coronary sinus on the guide wire (118). See line 10 of the abstract for the device being used in the coronary sinus

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or the great vein of the heart, and column 2, lines 30-36 for the inner lumen of the device in the expanded configuration having an inner diameter approximately equal to the inner diameter of the vessel. Dahl et al. teach an electrode (14) that is sized and configured to be inserted into the great vein of the inferior vena cava. See Figure 1 and column 3, lines 43-52. The electrode is constrained to a reduced diameter for introduction into the vein and self-expands to its original diameter (which is selected in accordance with the vein into which the device is to be implanted so that the stent will intimately contact the inner wall of the vein when in place) once the constraining member is removed. See column 2, lines 30-38. The inferior vena cava is the largest venous structure in the body and has a mean diameter of 19-20mm, as evidenced by Siskin (*Inferior Vena Cava Filters*, see sections "Normal anatomy" and "Assessing the IVC"; <http://www.emedicine.com/radio/topic762.htm>). The coronary sinus is typically 10mm at its largest diameter, as evidenced by Smits (USPN 6,006,122; see abstract and column 4, lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Dahl et al. to modify the device of Mehra by making it sized for insertion into the great vein of the inferior vena cava. Therefore, if the modified device of Mehra is placed and deployed within the coronary sinus, which has a smaller diameter than the inferior vena cava, expansion of the device to its original diameter (which corresponds to the diameter of the inferior vena cava) will certainly apply a force along a portion of the atrial wall of the coronary sinus and reshape the mitral valve annulus. When used in this manner, the device of Mehra is providing as a mitral valve annulus device. Applicant is reminded that a

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recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The modified device of Mehra is capable of reshaping the mitral valve annulus when in the coronary sinus, thereby making the assembly capable of effecting the condition of the mitral valve annulus.

Response to Arguments

Applicant's arguments with respect to claim 26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

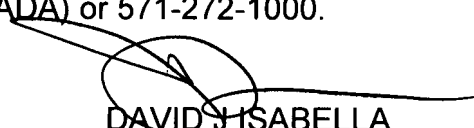
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
6/8/2007